

REMARKS

In the Office Action dated April 16, 2004, claims 13-17, 24-28, 30 and 31 are pending. Claims 13-17, 24-28, 30 and 31 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Frantz et al. (U.S. Patent No. 5,695,769).

This Response addresses the Examiner's rejection. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 13-17, 24-28, 30 and 31 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Frantz et al. (U.S. Patent No. 5,695,769), as evidenced by Barenholz et al (U.S. Patent No. 6,156,337). The Examiner has alleged that Frantz et al. teach a vaccine composition comprising a culture fluid fraction from a formalin-inactivated *Erysipelothrix rhusiopathiae*. The Examiner further alleges that the composition disclosed by Frantz et al. comprises Drakeol (i.e., a lecithin and mineral oil emulsion) at various concentrations, and between 0.7% to 3.2% TWEEN 80 and 0.3% to 1.8% SPAN. According to the Examiner, Frantz et al. teaches that the lecithin and mineral oil emulsion is present at a concentration of 5 to 40%, or 10%, and an amphiphilic surfactant is present at 8% v/v.

Applicants respectfully submit that independent claim 13 has been amended to specify that the *Erysipelothrix rhusiopathiae* fluid fraction is inactivated with beta-propiolactone (BPL). Support for BPL inactivation of the *Erysipelothrix rhusiopathiae* fluid fraction is found in the specification at page 4 line 18 and page 11, lines 23 and 24. Claim 15 has been deleted.

Applicants respectfully submit that Frantz et al. do not teach or suggest inactivating the *Erysipelothrix rhusiopathiae* fluid fraction with BPL. Additionally, those skilled in the art

would not have reasonably expected that a BPL-inactivated fluid fraction of *Erysipelothrix rhusiopathiae* would have sufficient immunoprotective effect. Therefore, Applicants respectfully submit that the subject matter presently claimed in claims 13, 16, 24 and 25, which relates to BPL-inactivated *Erysipelothrix rhusiopathiae* fluid fraction, is not anticipated by Frantz et.al.

Independent claim 17 has been amended to further define the adjuvant in the claimed vaccine composition to contain 2% v/v lecithin, about 18% v/v mineral oil, and about 8% v/v of an amphiphilic surfactant, with the remaining volume being a saline solution (No. 1 Adjuvant). Support for a vaccine composition containing No.1 Adjuvant is found in the specification at page 3, lines 34 and 35, page 4, lines 1 and 2, and page 18, line 1. As a result of the amendment to claim 17, claim 28 has been cancelled. Applicants respectfully submit that the subject matter of claims 17, 26-27 and 30-31 as presently amended is not anticipated by Frantz et al.

Applicants respectfully submit that Frantz et al. only disclose the preparation of a fluid fraction of an *Erysipelothrix rhusiopathiae* culture, inactivated by formalin. Frantz et al. do not teach combining the *Erysipelothrix rhusiopathiae* fluid fraction with any adjuvant, let alone the specific adjuvant as presently claimed. The disclosure of the '769 patent relating to the use of Drakeol, as referenced by the Examiner, is in the context of a *Pasteurella multocida* vaccine. There is no showing in the '769 patent that the *Erysipelothrix rhusiopathiae* preparation (absent any adjuvant) had any efficacy in protecting immunized animals. In fact, based on subsequent investigations of the present inventors, the *Erysipelothrix rhusiopathiae* preparation of the '769 patent would not have any immunoprotective effect absent an adjuvant.

Therefore, Applicants respectfully submit that Frantz et al. do not teach a vaccine composition containing an inactivated *Erysipelothrix rhusiopathiae* fluid fraction and a specific

adjuvant, as presently claimed. Further, there is no teaching or suggestion in Frantz et al. that would have provided those skilled in the art with a reasonable expectation of success that an inactivated *E. rhusiopathiae* fluid fraction, if combined with an specific adjuvant as claimed, would be effective in protecting vaccinated animals. As such, Applicants respectfully request the Examiner to withdraw the rejection to claims 13-17, 24-28, 30 and 31 under 35 U.S.C. §102(b)

Applicants further respectfully submit that claims 32-39 have been added. Claims 32-33 depend upon claims 17 and 30 and further define the inactivating agent as formalin or beta-propiolactone. Claims 34-39 are drawn to a vaccine composition comprising saponin as adjuvant. Support for claims 34-39 is found in the specification at page 8, lines 4-6. Applicants respectfully submit that no new matter has been added by claims 32-39.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein

Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

PIB/XZ/JM:ab